

REMARKS

Applicants thank the Examiner for the consideration given the present application. Claim 10 has been cancelled herein and Claims 1-9 and 11-57 remain pending in the present application.

The Rejections under 35 U.S.C. § 112

First Paragraph of §112

Claim 10 is rejected under 35 U.S.C. § 112, first paragraph. The Examiner states that, while the specification is enabling for the addition of an "asparagine-reducing enzyme" (asparaginase), the specification does not reasonably provide enablement for any random method reaction of "reducing the level of asparagines in roasted coffee beans." (quoting Claim 10). While Applicants respectfully disagree with the Examiner's assessment of Claim 10, in a sincere effort to advance prosecution of this case, Applicants have here in provisionally cancelled Claim 10, thereby preserving to right to further pursue the subject matter of Claim 10 at a later time if so desired. In view of this provisional cancellation, Applicants respectfully assert the rejection under 35 U.S.C. §112, first paragraph is moot.

Second Paragraph of §112

Claims 15-24, 33-39 and 50-57 have been rejected under 35 U.S.C. § 112, second paragraph for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. Specifically, the Examiner indicates that the terms "reduced," "asparagine-reducing enzyme" and "low" are not clearly defined in the present application. Each term is addressed in turn below.

First, the Examiner rejects Claims 15-24, 33-39 and 50-57 for the use of the term "reduced" therein. Specifically, the Examiner states that "reduced" is a relative term which renders the claim indefinite because it is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention." The Examiner continues to say "[a] product, as it stands in its current state, cannot simply be "reduced," without reference to a standard or to the previous condition.

Applicants respectfully traverse the Examiner's rejection based on the use of the term "reduced," which is defined as "to lessen in extent, amount, number, degree or price." The American Heritage Dictionary, 2nd Ed., Houghton Mifflin Company, Boston (1991). It would be obvious to one skilled in the art that the term "reduced," as used in the presently rejected claims, means that the level of asparagine/acrylamide is less in the claimed coffee beans than it would

ordinarily be in untreated coffee beans, i.e. coffee beans not exposed to asparagine-reducing enzymes. Thus, the term "reduced" means that the coffee beans have been treated with an enzyme such that the level of asparagine/acrylamide is less than what it would be in untreated beans. Applicants respectfully assert that one skilled in the art would understand that the use of the term "reduced" in the present claims describes the level of asparagine or acrylamide in treated coffee beans as compared to the level present in untreated beans. Therefore, it is respectfully asserted that the term "reduced" in the presently rejected claims does indeed provide a standard for ascertaining the meaning, such that one skilled in the art would be reasonably apprised of the scope of the claimed invention.

Second, the Examiner has rejected Claims 1-5 and 11-14 under the second paragraph of §112 for the incorporation of the word "asparagine-reducing enzyme," which the Examiner believes may be misleading. Specifically, the Examiner states that asparagine is "not an actual oxido-reductase class of enzymes," but rather, belongs to the hydrolase class of enzymes. The Examiner continues by saying that "while Applicant presumably intends this term to broadly encompass any enzyme which reduces the amount of asparagine in the product, it is technically improper." Finally, the Examiner concludes by quoting Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350 (Fed Cir. 1999) which says that where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term.

Applicants respectfully traverse this rejection. The term "reducing," as used within the phrase "asparagine-reducing enzyme," refers not to a class of enzymes, but rather to their functionality. Moreover, contrary to the Examiner's contention, the term "asparagine-reducing enzyme" is fully defined in the present specification. Specifically, in the present specification, both of the foregoing concerns are addressed as the term "asparagine-reducing enzyme" is defined as "any enzyme capable of both *reducing the level* of asparagine in coffee beans," and "*hydrolyzing* the amide group of free asparagine." (emphasis added) Specification, page 7. There is no mention of enzyme class or reduction reactions, such that one skilled in the art would be misled as to the meaning of the term as the Examiner claims. Indeed, in light of the foregoing definitions, Applicants respectfully assert that "asparagine-reducing enzyme" is clearly defined in the present specification such that one skilled in the art would understand that "asparagine-reducing" relates to the level of asparagine rather than the class of the enzyme described therein.

Thus, for these reasons, Applicants respectfully traverse the Examiner's rejection of the use of the term "asparagine-reducing enzyme" under the second paragraph of §112.

Finally, the Examiner has rejected Claims 51, 53, 55 and 57 under the second paragraph of §112, saying that the term "low" is a relative term that renders the foregoing claims indefinite. The Examiner states that "there is no standard or original amount of acrylamide provided in the specification such that one skilled in the art (or a consumer of the claimed article) would be apprised of what a "low" amount of acrylamide constituted in the article."

Applicants respectfully traverse the rejection of Claims 51, 53, 55 and 57 under the second paragraph of §112. Applicants respectfully point out that the term "low" as used in claims 51, 53, 55 and 57 is simply a word on a label, and thus, there is no definiteness issue surrounding its use in this context. A label either displays the term "low," or a similar term, or it doesn't. Therefore, because the presently rejected claims relate only to the labeling of the product, rather than the coffee, it is irrelevant what the term "low" actually means in these claims. (It will be left to the appropriate regulatory body to determine whether the use of the term "low" on a label, as claimed herein, is proper). Thus, Applicants respectfully traverse the rejection of Claims 51, 53, 55 and 57 under the second paragraph of §112.

The Provisional Obviousness-type Double Patenting Rejection

Claims 1 – 57 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting. Specifically, Claims 50-57 have been provisionally rejected as being unpatentable over the claims of co-pending Application No. 10/603,978, and Claims 1-57 have been provisionally rejected as being unpatentable over the claims of co-pending Application No. 10/606,137. Applicants respectfully traverse these rejections. Applicants submit the Examiner has failed to provide sufficient basis for asserting that the cited claims of the '978 or the '137 application teach or suggest the compositions and methods of the present application, the claims of which are directed to reducing asparagines or acrylamide in coffee-related products. Accordingly, it is respectfully requested that the obviousness-type double patenting rejections be withdrawn.

Synopsis of the Invention

With over 400 billion cups consumed every year, coffee is the world's most popular beverage. Although coffee has been enjoyed for thousands of years, researchers have only

recently discovered that coffee contains acrylamide. In April 2002, the Swedish National Food Administration and researchers from Stockholm University announced their findings that acrylamide, a potentially cancer-causing chemical, is formed in many types of foods and beverages that undergo heat processing. Acrylamide has a carcinogenic potency in rats that is similar to that of other carcinogens in food, but for humans, the relative potency in food and beverages is not known. Only limited human population data are available for acrylamide and these provide no evidence of cancer risk from occupational exposure. (FAO/WHO Consultation on the Health Implications of Acrylamide in Food: Summary Report; Geneva, Switzerland, 25-27 June 2002.)

Applicants have discovered that asparagine, a naturally occurring amino acid found in virtually all living systems, can form acrylamide when heated. Thus, materials richer in asparagine, when heated, tend to contain higher levels of acrylamide; this is especially the case when asparagine-containing materials are heated in the presence of reducing sugars.

While not being limited by theory, it is believed that acrylamide forms via the reaction mechanism set forth in Figure 1. It is believed that the alpha-amine group of free asparagine reacts with a carbonyl source, forming a Schiff base. Under heat, the Schiff base adduct decarboxylates, forming a product that can either: (1) hydrolyze to form beta-alanine amide (which can, under heat, further degrade to form acrylamide) or (2) decompose to form acrylamide and the corresponding imine. (Applicants have discovered that the circled precursor atoms comprise the carbons and nitrogens in acrylamide.)

Accordingly, Applicants have further discovered that acrylamide formation in roasted coffee beans can be reduced by removing the asparagine or converting the asparagine in the coffee beans to another substance before final roasting of the beans. When such beans containing reduced levels of asparagine undergo final roasting, the amount of acrylamide formed is reduced.

Applicants have found that adding an enzyme that hydrolyzes the amide group on the side chain of asparagine prior to final roasting of the coffee beans reduces the level of acrylamide present in the roasted coffee beans. While not being limited by theory, it is believed that the addition of such an enzyme degrades the side chain of asparagine, thus preventing the asparagine from forming acrylamide. In doing so, the amide bond is hydrolyzed and asparagine is converted to aspartic acid.

Although further research is needed to assess what health effects, if any, may result from human consumption of acrylamide at the levels commonly found in roasted coffee products, many consumers have voiced concern. Accordingly, it is an object of the present invention to provide a method for reducing the level of acrylamide in roasted coffee beans. It is also an object of the present invention to provide roasted coffee beans having reduced levels of acrylamide. Further, it

is an object of the present invention to provide an article of commerce that communicates to the consumer that a roasted coffee product has reduced or low levels of acrylamide.

The Rejection under 35 U.S.C. § 103

The Examiner has rejected Claims 1-57 under 35 U.S.C. § 103 as being unpatentable over Elder et al., Pub. No. 2004/0058054 (herein "Elder"). Specifically, the Examiner states that "Elder et al. discloses a method for reducing the amount of acrylamide in thermally treated processed foods." Moreover, the Examiner asserts that one such food that has tested positively for the presence of acrylamide is coffee, and in particular, roasted coffee beans. Also, the Examiner relies on Elder to teach that "[o]ne such method for inactivating is to contact asparagine with the enzyme asparaginase. This enzyme decomposes asparagine to aspartic acid and ammonia." Based on such statements, the Examiner concludes that it would have been obvious for one skilled in the art to add asparaginase to coffee beans prior to heating or cooking in order to reduce the formation of high levels of acrylamide in the final product. This is so because, as the Examiner asserts, the reference specifically disclosed that coffee beans were known to contain high levels of acrylamide, and also disclosed a specific effective means to solve this problem. Moreover, the Examiner concludes that the percent reduction of acrylamide claimed presently would have been inherent, and therefore, obvious, in view of the disclosure of Elder. Finally, the Examiner rejects Claims 50-57 saying that it would have been obvious to package and label the food products described in Elder. However, the Examiner continues to say that "if eventually the instant product claims directed to the food materials with reduced levels of asparagine [or acrylamide] were to be found allowable over the prior art, then the article container Claims 50-57 would also be allowable, if reasonably commensurate in scope. Applicants respectfully traverse this rejection.

The Examiner bears the burden of factually supporting any prima facie conclusion of obviousness. In determining the differences between the cited art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. See Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530 (Fe. Cir. 1983). Distilling the invention down to the "gist" or "thrust" of an invention disregards the requirement of analyzing the subject matter "as a whole." See W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983). Inventors of unobvious compositions, such as those of the present invention, enjoy a *presumption* of non-obviousness, which must then be overcome by the Examiner establishing a case of prima facie obviousness by the appropriate standard. If the Examiner does not prove a prima facie case of unpatentability,

then without more, the Applicant is entitled to grant of the patent. See In re Oetiker, 977 F.2d 1443.

To establish a prima facie case of obviousness under 35 U.S.C. §103, the Examiner must meet three basic criteria. First, there must be some suggestion or motivation, either in the reference itself, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the cited reference must teach or suggest *all* the claim limitations. See, for example, In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991). Appellants respectfully assert that the Office Action fails to establish any of these criteria, and thus, fails to make a prima facie case of obviousness under 35 U.S.C. § 103.

First, there is no suggestion or motivation to modify the reference. Elder very generally discusses the reduction of acrylamide in thermally processed foods by “inactivating asparagine.” However, this broad claim, without more, does not provide the motivation necessary to make obvious the specific methods and compositions disclosed presently for actually reducing acrylamide in coffee and coffee beans. Elder’s disclosure includes coffee and coffee beans among a long list of examples of foods which contain acrylamide, however, at no time does Elder specifically teach how to reduce acrylamide in coffee or coffee beans. Indeed, Elder does not even claim reduction of acrylamide in coffee beans, choosing instead to focus on rice, wheat, corn, barley and other like carbohydrates. Due to this lack of disclosure regarding coffee beans, Applicants respectfully assert that there is no suggestion or motivation to modify Elder such that the present invention is obvious in view thereof. For this reason alone, Applicants respectfully assert that a prima facie case of obviousness has not been established.

Second, there is no reasonable expectation of success as Elder fails to teach a method for acrylamide reduction in any food, but in particular, in coffee beans. As aforementioned, Elder generally discusses “inactivating asparagine” in foods, yet fails to provide any practical teachings relating thereto, even though the claims are directed to food products. Moreover, there is no teaching or suggestion in either the examples, or the specification, of Elder of a method by which to reduce the level of asparagine or acrylamide in a food product (and particularly coffee beans) by, for example, at least about 10%, at least about 30%, etc., up to at least about 90%, as presently taught and claimed by Applicants. Similarly, there is no teaching or suggestion in Elder of roasted coffee beans that have acrylamide levels below about 160 ppb, below about 150 ppb, etc. down to a level below about 10 ppb, as presently taught and claimed by Applicants. Rather, the Elder examples test only a chemical reaction (or the inhibition thereof) of a few chemicals independent of any food product. Specifically, contrary to the Examiner’s assertion in the last

sentence on page 5 of the Action, Example 5 in Elder deals only with the combination of asparagine, glucose and asparaginase in a laboratory setting. (Notably this is the only example having anything to do with *preventing* acrylamide formation.) There is no showing that such an example is in any way representative of what would occur if the method disclosed therein was carried out using an actual food product. Without such a correlation, it cannot be said that Elder teaches the subject matter of Applicants independent claims. As a result, it cannot be said that Elder provides *any* likelihood that the findings presented therein could be produced in food products, and in particular, in coffee and coffee beans. Therefore, Applicants respectfully assert that because Elder merely sets forth very general teachings around acrylamide reduction in certain food products, it provides no reasonable expectation of success of providing coffee beans or coffee products have reduced acrylamide levels. For this additional reason, Applicants respectfully assert that a prima facie case of obviousness has not been established.


Finally, there is no teaching of all the claim limitations. Again, Elder fails to teach a method of reducing the level of asparagine/acrylamide in coffee or coffee beans. The fact that Elder mentions coffee beans among a list of food products that contain acrylamide hardly amounts to teaching a method for reducing the level of asparagine or acrylamide therein. As discussed above, there is no discussion in Elder relating to reducing the level of asparagine/acrylamide in coffee or coffee beans. Therefore, because there is no teaching of all claim limitations, Applicants respectfully assert that a prima facie case of obviousness has not been established for any of Applicants' claims. As discussed above, the Examiner has pointed to no teaching in Elder that teaches or suggests the specific claim limitations - concerning level of asparagines or acrylamide reduction, or the resulting level of acrylamide, in coffee beans - that are included in many of Applicants' claims. Clearly, Elder cannot be said to render obvious such claims, particularly in view of the very limited disclosure around how one reduces such levels in food products.

Findings of fact relied upon in making the obviousness rejection must be supported by substantial evidence within the record. See In re Gartside, 203 F.3d 1305, 1315 (Fed. Cir. 2000). Appellants respectfully assert that, for all of the above reasons, the Examiner has failed to support the obviousness rejection with substantial evidence, and thus, has failed to establish a prima facie case of obviousness under 35 U.S.C. § 103. Therefore, Appellants respectfully request the rejection under 35 U.S.C. § 103 be withdrawn.

CONCLUSION

In view of the foregoing, it is respectfully submitted that the Examiner's rejections under 35 U.S.C. §§ 112 and 103, and the Provisional Obviousness-type Double Patenting Rejection, have all been overcome. Withdrawal of these rejections is respectfully requested.

Respectfully submitted,

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